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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,048	08/20/2007	Grete Kornerup	12706-44	8963

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EXAMINER	
YEH, JENNER	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
08/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,048	KORNERUP ET AL.	
	Examiner	Art Unit	
	JENNER YEH	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/2006, 3/26/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-8, 11, 12, 14, 18, 19 and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Teissen-Simony (US 5522803).

4. RE claims 1, 8, 23, 24, 26 and 27, Teissen-Simony discloses an infusion set comprising an infusion part 1, "cannula housing", for insertion into a patient and a connector 3, "connecting hub", a tube 4, "hose" connecting the infusion part with a medical device, the connector 3 being

axially displaceable relative to the infusion part 2 and being releasably connectable to the infusion part (Figure 1; Col 1, lines 7-20), the infusion part comprising:

a plaster adhesive support (Col 7, lines 18-25);

a base connected to the adhesive support, the base part having a lower surface, an upper surface, a first set of guides 15/16 and at least two retention devices 17/18, "locking openings", for releasably locking the connector 3 to the infusion part 2 (Figure 8; Col 4, line 57 to Col 5, line 34), the retention devices extending from the upper surface of the base (Figure 6);

a first cannula 2 extending outwardly from the base and being in fluid communication with a cavity 13, the cavity being adapted to receive a second cannula 40 extending from the connector 3, where the second cannula is in fluid communication with the tube 4 (Figures 5 and 13; Col 6, lines 17-30); and

a connector 3 comprising a second set of guides 21/22, "guide pins", adapted to fit with the first set of guides 17/18 and at least two arms 31/32, "locking pins", adapted to fit with the retention devices 17/18 (Figures 8 and 13; Col 4, line 57- Col 5, line 34).

5. RE claim 2, Teissen-Simony discloses connector 3 symmetrical relative to a main plane of the connector (Figure 16; See reference number 41, needle hub, which has the same shape as connector 3; Col 6, lines 31-37) and symmetrical relative to a plane perpendicular to the main plane and parallel to the central axis (Figure 13).

6. RE claims 3 and 4, Teissen-Simony discloses the arms 31/32 are flexibly connected to the second set of guides 21/22 in order for the arms to be able to move in the direction perpendicular to the base (Figure 13; Col 6, lines 10-16), where the connection between each arm 31/32 and the second set of guides 21/22 comprises at least one groove (Figure 13).

7. RE claims 5, 6, 11 and 12, Teissen-Simony discloses the retention devices 17/18 flexibly connected to the base and positioned on two flaps on the base, where each of the retention devices comprises a triangular-shaped step (Figure 8).

8. RE claim 7, Teissen-Simony discloses the cannula 2 passes through the adhesive support (Col 7, lines 18-26; Figures 5 and 9; ie. adhesive support is applied to platform 35, through which cannula 2 extends).

9. RE claim 14, Teissen-Simony discloses the medical device is an insulin pump (Col 4, lines 16-22).

10. RE claim 18, Teissen-Simony discloses the infusion part 1, "cannula housing" and connector 3 comprise polypropylene (Col 7, lines 34-36).

11. RE claim 19, Teissen-Simony discloses the second cannula 40 extends from a central part of the connector and the second cannula is recessed relative to a front portion of the central part (Figure 13) and at least one of the first set of guides 15/16 comprises at least two stabilizing fins (Figure 6; Guides 15/16 comprise stabilizing fins for bore 10).

12. RE claims 22 and 25, Teissen-Simony discloses a membrane 12 covering cavity 13 (Figure 5; Col 4, lines 45-49).

13. Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunn et al (US 2004/0158207).

14. RE claims 1, Hunn et al disclose an infusion set comprising an infusion part 1, "base body", for insertion into a patient and a connector 9, "plug", for connecting the infusion part 1 with a medical device through a tube 12, the connector 9 being axially displaceable relative to

the infusion part 1 and being releasably connectable to the infusion part (Figure 1; paragraph 0068), the infusion part comprising:

a plaster adhesive support 2 (paragraph 0064);

a base connected to the adhesive support, the base part having a lower surface, an upper surface, a first set of guides 14 and at least two retention devices for releasably locking the connector 9 to the infusion part 1, the retention devices 1b extending from the upper surface of the base (Figures 6 and 7; paragraphs 0069-0070);

a first cannula 3 extending outwardly from the base and being in fluid communication with a cavity 5, "holder", the cavity being adapted to receive a second cannula 10, "plug cannula", extending from the connector 9, where the second cannula is in fluid communication with the tube 12 (Figure 5); and

a connector 9 comprising a second set of guides (not shown in Figures), adapted to fit with the first set of guides 14 and at least two arms 15 adapted to fit with the retention devices 1b (Figures 6 and 7, paragraphs 0069-0070).

15. RE claim 7, Hunn et al disclose cannula 3 passing through adhesive support 2 (Figure 3).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (US 5522803) in view of Wojcik (US 6572586).

18. RE claim 9, Teissen-Simony discloses all the claimed elements, as discussed above, and discloses that the connector and infusion part can comprise any suitable plastic material (Col 4, lines 45-49). Teissen-Simony does not disclose the connector and infusion part comprising two different plastics material. Wojcik teaches suitable plastic materials such as polypropylene, polycarbonate or polyurethane that can be used to manufacture infusion set bases (Col 4, lines 49-51) or infusion set connectors (Col 5, lines 49-51).

It would have been obvious to one of ordinary skill in the art to manufacture Teissen-Simony's infusion part and connector such that both parts comprise different plastics as an obvious matter of design choice; one of ordinary skill in the art could manufacture the two parts separately using whichever materials were most economical to the design.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (US 5522803) in view of Reiterman (US 3670727).

20. RE claim 10, Teissen-Simony discloses all the claimed elements, as discussed above, but does not disclose the infusion part and the connector being of two different visual tones. Reiterman teaches an infusion set where a base of the infusion set, "wings", is of a different color

than the rest of the infusion set (Col 2, lines 42-48; Figures 1 and 2). Reiterman teaches that using different colors helps identify and differentiate between different bases (Co 2, lines 42-48).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Teissen-Simony's infusion set such that the connector and infusion part were of different colors, a taught by Reiterman, as an obvious matter of design choice and to easily identify infusion sets with different cannulas.

21. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (US 5522803).

22. RE claim 13, Teissen-Simony discloses all the claimed elements, as discussed above, but does not disclose the tube fastened to the connector by glue. Use of glue to connect two components is well known in the art, and Teissen-Simony teach that glue is well known and obvious to one of ordinary skill in the art that adhesive is a means with which to assemble two different components (Col 7, lines 42-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect Teissen-Simony's tube to the connector with glue to achieve the predictable result of assembling separate components.

23. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (US 5522803) in view of Brantigan (US 3893448).

24. RE claims 15 and 16, Teissen-Simony discloses all the claimed elements, as discussed above, and disclose cannula 2 is a soft cannula manufactured with a suitable plastic material (Col 4, lines 16-22). Teissen-Simony does not disclose the cannula made from a thermoplastic elastomer such as silicone rubber. Brantigan teaches a cannula for insertion into a patient where the cannula is made of silicone rubber (Col 2, lines 58-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Teissen-Simony's cannula such that it is manufactured from silicone rubber, as taught by Brantigan, for the purpose of providing a soft cannula that can be safely inserted into patients.

25. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunn et al (US 2004/0158207) in view of Gaba (US 5697907).

26. RE claims 20 and 21, Hunn et al disclose an injector device for the subcutaneous introduction of the first cannula, the injector device comprising a housing, a back and longitudinally extending guide (Figure 9), a slidable member 7/27, "needle carrier", which is longitudinally slidable within the housing (See Figures 9 and 10), a needle 8 for insertion in the cavity of the first cannula (Figure 2, paragraph 0073) , a spring 22 located between the back of the housing and the longitudinally slidable member (Figure 9), locking members 28b for maintaining the spring 22 in a compressed state (Figure 9, paragraph 0073) and release members 25, "triggering button", for disengaging the locking members (Figure 9, paragraph 0073). Hunn

et al do not disclose a pivoting member pivotable from one position allowing for insertion of the needle into a position where the pivoting member embraces the needle.

Gaba teaches an insertion needle device with where the insertion needle 135 is contained within a housing 342 that has a pivotable member 348, "retainer", that is pivotable between one position where the needle can be extended and inserted into a patient (Figure 13) and a second position where the pivotable member 348 embraces the needle (Figure 14). Gaba teaches that the pivotable member functions as a safety device to prevent the needle from extending out after insertion (Col 5, line 61 to Col 6, line 7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Hunn's insertion device to include a pivotable member, as taught by Gaba, for the purpose of providing enhanced safety precautions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNER YEH whose telephone number is (571)270-7836. The examiner can normally be reached on Monday-Thursday, 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. Y./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763